

REMARKS

Claims 2, 42, and 44 are canceled herewith. Thus, pursuant to the entry of the instant amendment, claims 1, 3-7, 24-28, 30-41, and 43 are pending, with claims 25-28, 32-35, 37-39, and 43 apparently withdrawn from consideration¹ as directed to non-elected inventions (methods of Groups III - VIII).

In an effort to expedite prosecution, independent claims 1 and 24 have been amended to incorporate the limitations of claim 2 (i.e., "wherein R6 is hydrogen"), designated allowable by the Examiner in the previous office action. This amendment necessitated minor revision to claims 6, 30, 32, 40, and 43 as well the cancellation of now redundant claims 2, 42, and 44. Claims 4, 6, 24, and 30 have also been amended in accordance with the Examiner's suggestion, to address allegations of indefiniteness. Thus, it would seem that claims 1 and 24, as well as the presently pending dependents thereof (i.e., claims 3-7, 30-41, and 43) are in condition for allowance. An early indication of such is respectfully requested.

Support for the claims as amended herewith is found in the specification as originally filed, particularly at page 8, lines 6-7 ("Preferably, residue R6 is hydrogen."). Thus, Applicants respectfully submit that no new matter has been added. However, Applicants reiterate that the amendments are presented solely for the purpose of expediting prosecution and should not be construed as Applicants' agreement with or acquiescence to the grounds of rejection previously set forth.

¹ Applicants note that the recitation of withdrawn claims set forth in the Office Action Summary page at line 4a) ("claims 25-28, 32-35, 37-39, 42, and 43") does not agree with the recitation of withdrawn claims set forth in the body of the Office Action at page 5 ("claims 24-28 and 30-44 are withdrawn from further consideration"). Nor does the recitation of examined claims set forth on the summary (claims 1-7, 24, 30-31, 36, 41, 42, and 44) agree with that set forth in the body, either at page 5 ("claims 1-7") or at page 9 ("claims 1-7, 24, 30-31, 36, 40-41, and 44"). The confusion of the record is addressed in greater detail hereinbelow.

Turning to the outstanding Office Action of September 24, 2009:

Election/Restriction:

As noted above, there is substantial confusion on the record as to which claims have been examined, which claims have been withdrawn and what precisely the Examiner considers the elected invention to be. For example, from a review of pages 4 and 5 of the outstanding office action, it would seem that there are 8 distinct categories of invention (enumerated as Groups I – VIII), with examination extended to both elected Group I, drawn to a process of making a compound of formula [A] (claims 1-7), and rejoined Group II, drawn to a process of making an intermediate compound of formula [B] (claims 24, 30-31, 36, 40-41 and 44). While Applicants continue to dispute the Examiner's erroneous application of the PCT rules governing unity of invention,² the point seems moot given that all but claims 25-28 are presently in condition for allowance. Accordingly, while Applicants acquiesce to the withdrawal of claims 25-28, they respectfully request reconsideration and rejoinder of claims 24, 30-41, and 43 in their entirety.

Section 112 Rejections:

Claims 1 and 5 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. According to the Examiner, the specification fails to adequately support and enable:

- (a) All potential "1,2,4-triazolyl forming reagents", with support being limited instead to only "1,3,5-triazine, formadine, and formamidine salts" (claim 1);

² The Examiner's attention is directed to Appendix B of the Administrative Instructions of the PCT, under heading (c) Independent and Dependent Claims: "Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By 'dependent' claim is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression 'category of claim' referring to the classification of claims according to the subject matter of the invention claimed for example, product, process, use or apparatus or means, etc.).". Pending claims 3-7, 30-41, and 43 are all process claims that depend directly or indirectly from elected claim 1. Accordingly, restriction within this grouping is in conflict with the administrative instructions and therefore improper.

- (b) All potential “protecting groups”, with support being limited instead to R2 as hydrogen (claims 1 and 24);
- (c) All “derivatives” of formadinium salts, with support being limited instead to formadinium salts (claim 6); and
- (d) All “residues”, with support being limited instead to the stated groups, i.e., hydrocarbon (claims 24, 30, and 42).

The Examiner applied a similar reasoning in rejecting claims 1, 4, 6, 24, 30, and 42 under 35 U.S.C. § 112, second paragraph, further characterizing the above-noted terminology as so unclear and/or indefinite as to render unknown the metes and bound of the claim at issue. The Examiner also pointed to issues of indefiniteness in claim 4, characterizing as unclear the phrase “into a different salt”.

At the outset, Applicants wish to remind the Examiner that the test for **enablement** under 35 U.S.C. § 112, first paragraph is substantially different from the test for **clarity and precision** under 35 U.S.C. § 112, second paragraph. Whereas the test of enablement is *whether one reasonably skilled in the art could make and use the claimed invention from the disclosures in the patent coupled with information known in the art without undue experimentation*, the test for clarity and precision is *whether one of ordinary skill in the art would understand the bounds or the claim, when read in light of the specification and in the context of the prior art*. In the context of enablement, the burden is on the Examiner to put forth evidence affirmatively demonstrating why the claimed method **cannot** not be performed without undue experimentation. Likewise, when considering the clarity and precision of claim language, the burden is on the Examiner to analyze the language not in a vacuum but rather in light of the specification, the teachings of the prior, and the reasonable interpretation given by one of ordinary skill before arriving at a finding of indefiniteness.

In this case, Applicants respectfully submit that the Examiner's conclusory statements regarding enablement and clarity lack the requisite foundation and evidentiary support are therefore *per se* improper. Nevertheless, in an effort to expedite prosecution, Applicants have revised or canceled the objectionable terminology from the claims 4, 6, 24, and 30, thereby rendering moot both the Examiner's concerns.

As for the above-noted item (a), Applicants respectfully disagree with the Examiner's characterization of the phrase "1,2,4-triazolyl forming reagents" and wish to remind the Examiner that "[b]readth of a claim is not to be equated with indefiniteness". See M.P.E.P § 2173.04 citing to *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). Furthermore, a specification is presumed to be in compliance with the enablement requirement of section 112, first paragraph, with the burden being on the Examiner to establish a reasonable basis to question enablement, with reference to specific supporting evidence. In this case, the Examiner's summary conclusion that the recitation of "1,3,5-triazine, formadine, and formamidinium salts" is insufficient to enable and define the genus of "1,2,4-triazolyl forming reagents" is not only incomplete but inaccurate. Contrary to the suggestion, Applicants respectfully submit that one of skill in the art would indeed be reasonably apprised of the metes and bounds of the term, particularly when read in the conjunction with the accompanying specification that expressly defines 1,2,4-triazolyl forming reagents as "those that form with the R-NH-NH in 5-position of the indole ring in formula [B] a 5-(1,2,4-triazol-1-yl) moiety". See page 21, lines 15-17. Given the guidance and direction of the instant specification, one of ordinary skill could readily, indeed routinely, extrapolate from illustrative examples to the broader genus of forming agents presently claimed. Thus, Applicants respectfully submit that the scope of "1,2,4-triazolyl forming reagents" is both adequately enabled and defined, thereby complying with the dictates of 35 U.S.C. § 112.

For similar reasons, Applicants traverse the Examiner's characterization of the term "protecting groups" as lacking clarity and enablement. The study of protective chemistry is a predictable science well understood by those of skill in the art, one that has evolved to the level of routine with web sites and databases readily available to assist one in achieving a "desired synthetic end-point by leveraging existing data on reaction conditions and conditions under which protecting groups are stable or labile."³ This coupled with the extensive guidance and exhaustive examples set forth in the accompanying specification (see page 19, line 20 to page 20, line 21) supports a finding of both enablement and precision.

Thus, Applicants respectfully submit that the claims as amended are in full compliance with the requirements of 35 U.S.C. § 112. As such, Applicants respectfully request reconsideration and withdrawal of the outstanding rejections of claims 1, 4, 6, 24, and 30 in view of the amendments and remarks herein.

CONCLUSION

The Office Action of September 24, 2009 set a three-month shortened statutory period for response. Accordingly, response is due on or before **December 24, 2009**. Applicants submit that this response is timely and no additional fees, apart from those included herewith, are required. However, in the event that further fees are required to enter the instant response and/or maintain the pendency of this application, the Commissioner is authorized to charge such fees to our Deposit Account No. 50-2101.

³ See <http://accelrys.com/products/accord/chemical-databases/protecting-groups.html>.

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If the Examiner has any questions or concerns regarding this communication, she is invited to contact the undersigned.

Respectfully submitted,

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